

REMARKS

Rejection under 35 U.S.C. § 102

Claims 1, 4-6, 9-11, 13, and 16-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2001/0007950 (hereinafter referred to as “North”).

Applicant notes that claims 6-12 and 19-23 have been cancelled without prejudice for the purpose of allowing the entry of claims 24-31 without paying additional new claim fees. Accordingly, the rejection of claims 6-12 and 19-23 is not addressed herein. Claims 24-31 are discussed separately below.

Claim 1

Claim 1 recites:

a pulse generator that outputs at least two sets of electrical stimulation pulses having differing characteristics, wherein each set of stimulation pulses are associated with a unique stimulation setting, and wherein the pulse generator generates its outputs as directed by the microprocessor in accordance with at least one repetition parameter associated with each unique stimulation setting.

Applicant submits that the “programming codes” or “pulse parameters” of North do not meet the “repetition parameter” element of claim 1. Specifically, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added).

North merely discloses a “fully automated computer controlled system” for adjusting the settings of a neurostimulation device. As shown in North, FIG.s 7A, 7B, 8A, 8B, 9A, 9B, 10A, 10B, and 11 depict various user-interface screens of a software program used to adjust

the settings of a neurostimulation device. These screens prompt the user to indicate locations on the body in which the patient perceives stimulation and the subjective quality of the stimulation.

Furthermore, as described by North, a programming “code” is merely used as a generic term for a radio frequency code transmitted to an implanted device to control its operation. *See paragraph [0008] of North.* The “pulse parameters” referred to by North merely include electrode configurations, pulse frequency, pulse width, and pulse amplitude. *See paragraph [0008] of North.*

In contrast, a repetition parameter is a parameter stored in an implantable stimulator that defines how many consecutive pulses associated with a specific set of pulse parameters are generated and delivered to living tissue before changing to another pulse associated with another set of pulse parameters. Applicant respectfully submits that the applied reference does not satisfy the requirements of 35 U.S.C. § 102, because mere general purpose “programming codes” and “pulse parameters” do not show the identical invention in as complete detail as recited by claim 1.

Therefore, claim 1 is not anticipated by North. Claims 4-6 depend from base claim 1 and, hence, are also not anticipated by North.

Claim 13

Claim 13 recites:

generating repeating electrical pulses according to the selected first stimulation setting wherein the selected first stimulation setting describes a repetition parameter for the repeating electrical pulses;...

generating a second set of repeating electrical pulses according to the at least one additional selected stimulation settings wherein the at least one additional selected stimulation setting describes a repetition parameter for the second set of repeating electrical pulses.

For the reasons discussed above in regard to claim 1, Applicant respectfully submits that North does not disclose each and every limitation of claim 13. Claims 16-18 depend from claim 13 and, hence, are also not anticipated.

Rejections under 35 U.S.C. § 103(a)

Claims 2-3, 7-8, 14-15, and 19-23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over North in view of U.S. Patent No. 5,038,781 (hereinafter referred to as “Lynch”).

Claim 12 is rejected under 35 U.S.C. § 103(a) as being unpatentable over North in view of Lynch in further view of U.S. Patent no. 6,016,447 (hereinafter referred to as “Juran”).

As previously discussed, claims 7-8, 12, and 19-23 are cancelled without prejudice. Accordingly, these claims are not addressed herein.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the applied reference (or references when combined) must teach or suggest all the claim limitations. *See MPEP § 2143.* Applicant respectfully submits that the applied references do not satisfy these criteria.

Claims 2-3 and 14-15 respectively depend from claims 1 and 13 and, hence, inherit all limitations of their base claim. For the reasons discussed above in regard to the rejection under 35 U.S.C. § 102(b), North does not teach or suggest each and every limitation of claims 1 and 13. Lynch and Juran are not relied upon to address the limitations of claims 1 and 13. Moreover, Lynch and Juran do not teach or suggest these limitations. Therefore, the applied references (either alone or in combination) do not teach or suggest each and every limitation of claims 2-3 and 14-15. A *prima facie* case of obviousness has not been established for these claims.

Skipping Parameter and Claims 2 and 14

Claims 2 and 14 recite “skipping parameters.”

The Examiner states that North discloses “skipping parameters that are associated with the stimulation settings.” Office Action, page 2. The Examiner points to paragraphs [0252] and [0253] of North to support this assertion.

Applicant is unable to find in North any reference or teaching of “skipping parameters.” Applicant submits that North discloses skipping or omitting performance of a portion of an adjustment algorithm associated with one or several simulation parameters.

Specifically, North discloses a “fully automated computer controlled system” for adjusting the settings of a neurostimulation device. As shown in North, FIG.s 7A, 7B, 8A, 8B, 9A, 9B, 10A, 10B, and 11 depict various user-interface screens of a software program used to adjust the settings of a neurostimulation device. These screens prompt the user to indicate locations on the body in which the patient perceives stimulation and the subjective quality of the stimulation. The screens involve determining a “threshold” parameter that defines the minimum amplitude necessary for the patient to perceive the stimulation on a single side of the body. *See* FIG. 8A of North. The screens also involve determining the minimum amplitude necessary for the patient to perceive the stimulation on both sides of the body. *See* FIG. 8B of North.

The logic step of North that is cited in the Office Action relates to output amplitude. Specifically, the logic step determines whether the single side threshold parameter equals the maximum output amplitude that can be generated by the stimulation device. If so, the software omits determining the bilateral threshold amplitude. Col. 31, lines 39-43. Specifically, if the maximum output amplitude has already been reached, there is no way to increase the amplitude anymore to determine the bilateral threshold amplitude.

Thus, North discloses a logic flow performed by software of a programming device that omits performance of certain steps upon a predefined condition. However, North does not disclose a parameter stored in an implantable stimulator that defines a number of cycles

within a predetermined number of stimulation cycles that a particular stimulation setting should not be used to generate a pulse. *See* paragraph [0052] of the application.

Lynch does not disclose a skipping parameter, but merely discloses skipping a pulse when an error in pulse parameter communication occurs as detected by a bit parity error detection scheme. Col. 13, lines 30-44. Juran does not disclose a skipping parameter, but rather, discloses reducing pulse amplitude to eliminate unnecessary pulse energy. Col. 1, lines 43-53. Accordingly, the applied references (either alone or in combination) do not teach or suggest each and every limitation of claims 2 and 14. A *prima facie* case of obviousness has not been established for these claims.

New Claims

Applicant has added new claims 24-31. These claims are supported by the original application and no new matter has been entered.

Claim 24 is directed to a method for stimulating living tissue that comprises:

stimulating living tissue(s) by (i) successively selecting a stimulation set from the plurality of stimulation sets in a cyclical manner; (ii) generating a pulse according to the pulse characteristic of the selected stimulation set; and (iii) delivering the generated pulse to living tissue(s) through electrodes according to the electrode configuration of the selected stimulation set.

Claim 28 is directed to an electrical stimulator that comprises:

a microprocessor operating under executable instructions that:

- (i) successively selects a stimulation set from the plurality of stimulation sets in a cyclical manner;
- (ii) loads the pulse characteristic into a pulse control associated with the pulse generator;
- (iii) configures an output switch matrix according to the electrode configuration of the selected stimulation set;
- (iv) causes the pulse generator to output at least one pulse after the loading and configuring; and
- (v) when the selected stimulation set is the at least one stimulation set associated with the repetition parameter, repeating (iv) according to the repetition parameter.

For the reasons discussed above, Applicant submits that the applied references (either individually or in combination) do not teach or suggest a "repetition parameter" as recited by claims 24 and 28. Accordingly, claims 24 and 28 are patentable over the applied references. Claims 25-27 and 29-31 respectively depend from claims 24 and 28 and, hence, are also patentable over the applied references.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue. Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2380, under Order No. 02-050 from which the undersigned is authorized to draw.

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Respectfully submitted,

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